

Questioning the “Right” in State Right to Try Laws: Assessing the Legality and Effectiveness of These Laws

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I. INTRODUCTION

Austin and Max Leclaire are fifteen year-old brothers from Pembroke, Massachusetts.¹ Both Austin and Max suffer from Duchenne muscular dystrophy, a degenerative and fatal disease of the muscles.² But over the past 144 weeks, the physical conditions of the brothers have progressed in opposite directions. Max has shown extreme progress—for example, he no longer requires a wheelchair and can now run and ride a bike—while Austin has declined, no longer able to walk, brush his teeth, or hold a water bottle.³ This drastic divergence in health outcomes stems from the brothers' unequal access to experimental drugs.

Max has been a participant in a promising new clinical trial where he has been given weekly infusions of the experimental drug known as Eteplirsen, which is manufactured by Sarepta Therapeutics, Inc. and intended to transform the disease into a milder form of muscular dystrophy that, while still chronic, is no longer fatal.⁴ Austin, however, was unable to participate in the trial due to his more advanced condition of the disease.⁵ It took over three years before the FDA created a clinical trial that Austin qualified to participate in, and during this waiting period he lost many crucial motor skills, such as the ability to transfer himself from his wheelchair to his bed.⁶ And for those individuals who never qualify for a clinical trial, their best hope is that the drug Eteplirsen will gain market approval by the FDA sooner rather than later.⁷ Unfortunately, this process may take anywhere from two to ten years.⁸

¹ Michael Ollove, *Right-to-Try for the Terminally Ill*, USA TODAY (June 19, 2014), <http://www.usatoday.com/story/news/nation/2014/06/19/stateline-fda-terminal-illness-drugs/10836705/> [https://perma.cc/FQ7V-7LD6].

² *Id.*

³ *Id.*

⁴ Darcy Olsen, *Dying Patients Should Have 'Right to Try' New Treatments*, TIME (Nov. 10, 2015), <http://time.com/4091290/right-to-try/> [https://perma.cc/AY76-ZU82].

⁵ Ollove, *supra* note 1. Refusal of access to clinical trials, as in Austin's case, is not uncommon for the terminally ill, as there are several barriers they may face to participation. Most notably, as a way to minimize the number of variables in the study, drug sponsors control the trials by requiring that applicants meet very specific eligibility criteria, and individuals with more complex illnesses or conditions that differ even slightly from the criteria being studied will be excluded. Rebecca Dresser, *The "Right to Try" Investigational Drugs: Science and Stories in the Access Debate*, 93 TEX. L. REV. 1631, 1635 (2015).

⁶ Olsen, *supra* note 4.

⁷ Ollove, *supra* note 1.

⁸ While several sources maintain that the drug approval process takes upwards of a decade, see, e.g., *Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion*, TUFTS CTR. FOR STUDY DRUG DEV. (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study [https://perma.cc/L4FH-E6YF], the FDA maintains that priority applications are approved within three years of submission and standard applications within five. FDA, FY 2010 PRESCRIPTION DRUG USER FEE ACT (PDUFA) PERFORMANCE REPORT 4 (2010), <http://www.fda.gov/downloads/AboutFDA/>

Law professor Michael Malinowski tells a different story regarding access to investigational drugs.⁹ His father, Joe, who had been diagnosed with a form of terminal cancer, sought and was able to secure experimental treatments.¹⁰ Initially, the drugs were successful and expanded Joe’s productive lifespan by fourteen years.¹¹ Encouraged by the positive results, when his condition began to deteriorate again many years later, Joe pursued more experimental treatments.¹² This time, however, the drugs sent Joe’s health into a serious decline, and he suffered devastating side effects before passing away.¹³

The heartbreaking stories of the Leclaire brothers and Joe Malinowski illustrate both sides of an emotionally charged debate amongst legal, ethical, and medical scholars alike. As a response to stories like the Leclaire brothers’ and with hopes of providing increased access to experimental drugs for terminally ill individuals, many states have passed Right to Try laws at a rapid pace within the last two years.¹⁴ These laws grant patients with terminal illnesses access to drugs and treatments that have passed preliminary safety testing, but have not yet been approved by the FDA.¹⁵ By eliminating the FDA from the drug approval process, the purpose of these laws is to pave an expedited path to access to promising experimental treatments by cutting the

ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/UCM243358.pdf [https://perma.cc/LJ25-J8X6].

⁹ Michael J. Malinowski, *Throwing Dirt on Doctor Frankenstein’s Grave: Access to Experimental Treatments at the End of Life*, 65 HASTINGS L.J. 615, 616–19 (2014).

¹⁰ *Id.* at 616.

¹¹ *Id.* at 617.

¹² *Id.* at 618.

¹³ *Id.*

¹⁴ See, e.g., Terminal Patients’ Right to Try Act, 2014 Ariz. Legis. Serv. H. Con. Res. 2005 (codified at ARIZ. REV. STAT. ANN. §§ 36-1311 to -1314 (West Supp. 2015)); Right to Try Act, 2014 Colo. Legis. Serv. Ch. 220 (H.B. 14-1281) (codified at COLO. REV. STAT. § § 25-45-101 to -108 (2015)); see also *infra* Part III.

¹⁵ Kimberly Leonard, *Seeking the Right to Try*, U.S. NEWS & WORLD REP. (Nov. 18, 2014), <http://www.usnews.com/news/articles/2014/11/18/right-to-try-laws-allowing-patients-to-try-experimental-drugs-bypass-fda> [https://perma.cc/7ANU-6L5A]; see also The Editorial Bd., *Quicker Access to Experimental Drugs*, N.Y. TIMES (Feb. 12, 2015), <http://www.nytimes.com/2015/02/12/opinion/quicker-access-to-experimental-drugs.html> [https://perma.cc/B32S-57LR] (noting that although these investigational drugs have passed initial safety testing, they are “still years away from reaching pharmacy shelves”). Only a certain “eligible patient” may take advantage of these laws, defined generally, with slight variations among the state laws, as someone who has an advanced or terminal illness, has considered all other FDA-approved treatment options, has given written, informed consent, and has physician endorsement. See, e.g., COLO. REV. STAT. § 25-45-103(1)(a); Right to Try Model Legislation § 1(2)(b) (Goldwater Inst. 2016), https://goldwater-media.s3.amazonaws.com/cms_page_media/2016/1/5/GoldwaterInstituteRighttoTryModel.pdf [https://perma.cc/EK2Y-FDMC]. An “advanced illness” or “terminal illness” is defined by statute as “a disease that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.” COLO. REV. STAT. § 25-45-103(3); see also Right to Try Model Legislation, *supra*, § 1(2)(a) (proposing a similar definition).

bureaucratic red tape that is manifested in the form of unnecessary paperwork and wait times.¹⁶ However, as stories such as Joe Malinowski's illustrate, the hope of prolonging the life of the terminally ill often overshadows the dangers that could arise from increased access.

The current FDA approval process requires manufacturing companies seeking to introduce drugs to the market to conduct animal testing and three phases of human clinical trials prior to submitting a New Drug Application (NDA) to the FDA for review.¹⁷ The NDA requires that a manufacturer present evidence at that time of submission of a drug's safety and efficacy.¹⁸ Because this process can be cumbersome, the FDA offers expanded access options through its compassionate use program.¹⁹ Individuals may qualify for compassionate use and obtain access to promising experimental drugs if they have either a "serious disease/condition" or an illness that is "immediately life threatening."²⁰ A treating physician must act as an individual's sponsor and, in addition to completing an application estimated by the FDA to take upwards of 100 hours, obtain drug company consent and IRB approval.²¹

Critics of the FDA's processes believe that individuals with serious or terminal illnesses do not have the luxury of waiting for either premarket approval or the granting of a compassionate use exception; therefore, in response to this concern, state legislatures have stepped in and attempted to remove barriers to access. Within the past two years alone, almost half of all states have passed Right to Try laws.²² Given the upsurge in this recent legislation and the sensitive subject matter of the laws, the policy debate regarding Right to Try laws has been heated, yet the legality of these statutes has not yet been seriously questioned.

However, it is probable that Right to Try laws violate the Supremacy Clause of the United States Constitution by encroaching on congressionally

¹⁶Christina Corieri, *The Right to Try*, GOLDWATER INST. (Jan. 20, 2015), <http://goldwaterinstitute.org/en/work/topics/healthcare/right-to-try/right-try/> [<https://perma.cc/DYF9-TFUE>].

¹⁷Ollove, *supra* note 1.

¹⁸*Id.*

¹⁹*Expanded Access: Information for Patients*, FDA, <http://www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm> [<https://perma.cc/P8AW-P5SE>] (last updated Mar. 3, 2016) [hereinafter *Information for Patients*]; see also 21 C.F.R. § 312.300 (2015).

²⁰*Information for Patients*, *supra* note 19 (defining both terms). Furthermore, there are several other qualifying criteria that must be met for individuals to qualify for compassionate use. For example, the FDA must determine that "[t]here is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition." *Id.*; see also 21 C.F.R. § 312.300(a); *Expanded Access and Expedited Approval of New Therapies Related to HIV/AIDS*, FDA, <http://www.fda.gov/ForPatients/Illness/HIVAIDS/Treatment/ucm134331.htm> [<https://perma.cc/NJ7E-2DKY>] (last updated Aug. 7, 2014) [hereinafter *New HIV/AIDS Therapies*].

²¹Leonard, *supra* note 15; see also *Information for Patients*, *supra* note 19.

²²See *infra* note 115.

mandated FDA authority to regulate the premarket drug approval process and ensure the safety and effectiveness of drugs on the market.²³ While the Food, Drug, and Cosmetic Act (FDCA)²⁴ does not contain an express preemption clause, it does state that federal rule governs if there is a “direct and positive conflict” with a state law.²⁵ A “direct conflict” exists between the FDCA and state Right to Try laws because it is impossible for organizations to comply with both laws, and the purpose of the FDA to regulate new drugs is undoubtedly frustrated.²⁶ Thus, a court would likely find that Right to Try laws are impliedly preempted.

In addition to questions surrounding the legality of Right to Try laws, there are also several policy implications to consider. Advocates of the laws contend that terminally ill individuals are in unique circumstances and should be exempt from unnecessary government interference, which is preventing them from obtaining potentially life-saving treatment.²⁷ They argue that physician support coupled with Phase I safety and toxicity testing provide adequate safeguards, beyond which individuals are capable of making their own treatment decisions, particularly when it is a question of life or death.²⁸

On the other hand, opponents of Right to Try legislation not only believe that the laws will result in negative policy outcomes, but also question their effectiveness. Many drug companies are concerned that providing Right to Try patients with access to experimental drugs will jeopardize ultimate FDA

²³ See *infra* Part IV.

²⁴ Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

²⁵ *Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (quoting Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (“Nothing in the amendments made by the Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a *direct and positive conflict* between such amendments and such provision of State law.” (emphasis added))).

²⁶ See, e.g., FDCA § 505(a), 21 U.S.C. § 355(a) (2012) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.”). If drug companies are able to provide drugs directly to patients without FDA involvement, the administration will no longer be able to monitor the effects of these investigational new drugs.

²⁷ See *infra* Part V.A. For example, physicians will arguably benefit the most from Right to Try laws because, under the legislation, they are no longer required to spend 100 hours filling out FDA-required paperwork in order to be granted a compassionate use exception by the FDA. Brady Dennis & Ariana Eunjung Cha, ‘Right to Try’ Laws Spur Debate over Dying Patients’ Access to Experimental Drugs, WASH. POST (May 16, 2014), http://www.washingtonpost.com/national/health-science/right-to-try-laws-spur-debate-over-dying-patients-access-to-experimental-drugs/2014/05/16/820e08c8-dcfa-11e3-b745-87d39690c5c0_story.html [https://perma.cc/NS8L-445Z].

²⁸ Dresser, *supra* note 5, at 1632.

approval.²⁹ In addition, providing limited amounts of experimental drugs is costly, and the risk of potential liability is high.³⁰ If drug companies are unwilling to provide experimental drugs directly to patients as Right to Try laws allow, terminally ill patients will not receive treatments any faster than they would proceeding under the FDA's compassionate use program, as the state laws do not coerce drug manufacturers into participation.³¹ Without incentives for drug manufacturers to provide experimental treatments, the value of Right to Try laws may be severely limited.

This Note proposes a threefold solution for the future of Right to Try laws. First, the FDA should promulgate a regulation or guidance clearly articulating the viewpoint that these state laws are unconstitutional. Next, if such laws remain on the books, a party with standing to sue, such as a drug company, should file a lawsuit seeking declaratory judgment on the legality of Right to Try laws. Finally, the FDA must work with state and federal legislators to undertake a series of reform measures that will result in a more streamlined compassionate use program, while at the same time fulfilling its mission that drugs remain safe and effective.

This Note proceeds as follows: Part II provides background information on the history of the FDA, the drug approval process, and compassionate use. It then examines the derivation of Right to Try laws, dating back to a 2006 D.C. Circuit decision in *Abigail Alliance*.³² Part III provides a more detailed overview of Right to Try legislation, and Part IV discusses the law of preemption and its application to Right to Try laws. Part V addresses policy concerns surrounding the state laws before Part VI offers a view of the future of Right to Try legislation.

²⁹ Jason Millman, *Voters in Arizona Just Overwhelmingly Backed a 'Dallas Buyers Club' Law. Will It Help Patients?*, WASH. POST (Nov. 5, 2014), <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/11/05/voters-in-arizona-just-overwhelmingly-backed-a-dallas-buyers-club-law-will-it-help-patients/> [<https://perma.cc/3G3E-76QT>]. The FDA may view drug companies that provide access via Right to Try laws as circumventing federal authority; alternatively, if negative outcomes arise from providing the drugs early, it is likely the drugs will never gain full market approval.

³⁰ See Leonard, *supra* note 15.

³¹ Whether one proceeds through the FDA-sponsored compassionate use program or Right to Try laws, approval of a drug company must be obtained in both instances. David Gorski, *The False Hope of "Right-to-Try" Metastasizes to Michigan*, SCI.-BASED MED. (July 21, 2014), <http://www.sciencebasedmedicine.org/the-false-hope-of-right-to-try-metastasizes-to-michigan/> [<https://perma.cc/3HTY-KWBL>].

³² *Abigail All. for Better Access to Developmental Drugs v. von Eschenbach (Alliance I)*, 445 F.3d 470 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007).

II. LAYING THE FOUNDATION

A. *The Role of the FDA*

The Food & Drug Administration (FDA) is the federal agency tasked with protecting the public against unsafe and mislabeled products.³³ This authority includes reviewing applications submitted by drug companies to sell drugs to the general public and deciding whether such drugs are safe, effective, and should be available for public treatment and consumption.³⁴ The FDA derives its authority from a series of federal statutes, including the Food, Drug, and Cosmetic Act (FDCA) of 1938 and the 1962 amendments to that Act, known as the Kefauver Harris Amendments.³⁵

1. *Background*

Historically, matters of health and safety were thought by many to be matters best fit for state regulation.³⁶ Although this was the initial viewpoint of the FDA as well, beginning in the early 1900s, Congress enacted a series of statutes and amendments that vastly enlarged the scope of federal power in this area. In 1906, Congress passed its first public health law, the Federal Food and Drugs Act, which prohibited the manufacture or shipment in interstate commerce of adulterated or misbranded drugs and served as a statutory supplement to state common-law liability.³⁷

By 1938, however, concerns over unsafe drugs and fraudulent marketing remained; therefore, Congress passed the FDCA to bolster consumer protection against harmful products.³⁸ The FDCA’s most significant contribution was the wide, sweeping authority it granted to the FDA to govern the premarket approval process of drugs. It required every drug manufacturer to submit an NDA to the FDA for review prior to selling drugs in the market.³⁹ Under the Act, the manufacturers were prohibited from distributing new drugs

³³ PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 24 (3d ed. 2007).

³⁴ Leonard, *supra* note 15.

³⁵ See *infra* Part II.A.1 and accompanying notes.

³⁶ *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (stating that the “regulation of health and safety matters is primarily, and historically, a matter of local concern”); *Metro. Life Ins. v. Massachusetts*, 471 U.S. 724, 756 (1985) (“States traditionally have had great latitude under their police powers to legislate as ‘to the protection of the lives, limbs, health, comfort, and quiet of all persons.’” (quoting *Slaughter-House Cases*, 83 U.S. (16 Wall.) 36, 62 (1872))).

³⁷ Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768; *Wyeth v. Levine*, 555 U.S. 555, 566 (2009).

³⁸ Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.); *Wyeth*, 555 U.S. at 566.

³⁹ FDCA § 505(a)–(b), 52 Stat. at 1052; *Wyeth*, 555 U.S. at 566.

until either the FDA affirmatively approved the application or sixty days passed after the application was filed.⁴⁰

The 1962 Kefauver-Harris Amendments enlarged the FDA's powers to "protect the public health" and "assure the safety, effectiveness, and reliability of drugs" even further.⁴¹ They did so by shifting the burden from the FDA to prove that a drug was unsafe, to the manufacturer, who was now required to affirmatively demonstrate that a drug was safe for consumption *and effective* before it could be marketed.⁴² Despite the appearance of a vast grant of federal power to the FDA, Congress also included within the amendments a clause limiting the scope of federal preemption of state law.⁴³ This savings clause provided that a provision of state law would only be invalidated upon a "direct and positive conflict" with the FDCA.⁴⁴

In 1976, Congress passed the Medical Device Amendments (MDA),⁴⁵ which created a comprehensive and multi-tiered scheme of federal regulation of the premarket approval of medical devices, which severely curbed states' authority over the subject.⁴⁶ This Act also included an express preemption

⁴⁰ FDCA § 505(c), 52 Stat. at 1052; *Wyeth*, 555 U.S. at 566.

⁴¹ Drug Amendments of 1962, Pub. L. No. 87-781, pmb., 76 Stat. 780, 780. The Drug Amendments of 1962 were commonly called the Kefauver-Harris Amendments, named after the two congressional sponsors: Sen. Estes Kefauver (D-Tenn.) and Rep. Oren Harris (D-Ark.). *Kefauver-Harris Amendments Revolutionized Drug Development*, FDA CONSUMER HEALTH INFO., Oct. 2012, at 1, <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM322886.pdf> [<https://perma.cc/JDQ7-UKFT>].

⁴² *Id.* §§ 102(c), 104(b), 76 Stat. at 781, 784; *Wyeth*, 555 U.S. at 567 ("[T]he [1962] amendments required the manufacturer to demonstrate that its drug was 'safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling' before it could distribute the drug."). The Kefauver-Harris Amendments largely originated due to public outrage over the discovery in the 1960s that a sedative prescribed to pregnant women to alleviate morning sickness was causing birth defects. *See* Leonard, *supra* note 15; *see also Kefauver-Harris Amendments Revolutionized Drug Development*, *supra* note 41, at 1.

⁴³ Drug Amendments of 1962 § 202, 76 Stat. at 793 ("Nothing in the amendments made by this Act to the [FDCA] shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.").

⁴⁴ *Wyeth*, 555 U.S. at 567 (quoting Drug Amendments of 1962 § 202, 76 Stat. at 793).

⁴⁵ Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. §§ 360c–360k, 379, 379a; 42 U.S.C. § 3512 (2012)).

⁴⁶ MDA § 2, 21 U.S.C. §§ 360e, 360i (2012); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–18 (2008) (describing the premarket approval application to require full reports of all studies and investigations into the safety and effectiveness of the drug at issue; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device" (quoting 21 U.S.C. § 360e(c)(1))); *Premarket Approval (PMA)*, FDA, <http://www.fda.gov/Medicaldevices/Deviceregulationandguidance/Howtomarketyourdevice/Premarketsubmissions/Premarketapprovalpma/Default.Htm> [<https://perma.cc/J8S3-U3HF>] (last updated Aug. 19, 2014).

provision.⁴⁷ And most recently, in 2012 Congress passed the Food and Drug Administration Safety and Innovation Act (FDASIA),⁴⁸ which “expands the FDA’s authorities and strengthens the Agency’s ability to safeguard and advance public health.”⁴⁹ FDASIA gives the FDA the authority to collect user fees to provide it with the funding necessary to complete both comprehensive and timely review of new products; provides for a new expedited drug development tool known as breakthrough therapy; and presents stakeholders with increased ways to offer input into FDA decision making.⁵⁰

2. Drug Approval Process

Pursuant to the FDCA, in order for drug companies to sell their drugs on the open market, they must first gain FDA approval.⁵¹ Initially, when a drug sponsor identifies a potential new drug, it will conduct preclinical animal testing to determine whether the molecule exhibits pharmacological activity and assess its acute toxicity potential, ultimately making an initial determination as to whether the product is safe for initial use in humans.⁵² Having decided a product is a viable candidate for human testing, the drug sponsor will then submit an Investigational New Drug (IND) application to the FDA, which includes the results of animal studies, manufacturing information, including the composition of the drug, and detailed protocols for proposed human testing, or clinical trials.⁵³ The purpose of the IND application is

⁴⁷ See MDA § 2, 21 U.S.C. § 360k(a) (“Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.”).

⁴⁸ Food and Drug Administration Safety and Improvement Act (FDASIA), Pub. L. No. 112-144, 126 Stat. 993 (2012) (codified as amended in scattered sections of 21 U.S.C.).

⁴⁹ *Food and Drug Administration Safety and Innovation Act (FDASIA)*, FDA, <http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCA/FDASIA/ucm20027187.htm> [<https://perma.cc/MT82-FVQS>] (last updated Oct. 6, 2015).

⁵⁰ *Id.*; see also FDASIA §§ 101–408, 902, 905, 126 Stat. at 996–1039, 1086–88, 1092.

⁵¹ FDCA § 505(a), 21 U.S.C. § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.”); see also *Development & Approval Process (Drugs)*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/> [<https://perma.cc/S3GA-R6LV>] (last updated Jan. 29, 2016).

⁵² *Investigational New Drug (IND) Application*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm> [<https://perma.cc/X29W-5AV8>] (last updated Oct. 27, 2014) [hereinafter *IND Application*].

⁵³ *Id.*

twofold. First, because most sponsors will conduct clinical trials in multiple states, the IND serves as an exemption to the statutory requirement that a drug must be FDA-approved prior to being transported across state lines.⁵⁴ Additionally, it allows the FDA time to complete its own preliminary review to ensure that the proposed clinical trials do not place the human subjects at an unreasonable risk of harm.⁵⁵ An institutional review board (IRB) also reviews the IND.⁵⁶ A drug sponsor must wait thirty days after the submission of the IND before it is permitted to begin clinical testing.⁵⁷

Clinical testing comprises three phases of human trials designed to test whether a drug is safe and effective for general public consumption.⁵⁸ After successful completion of all three phases of clinical trials—a process which can take several years⁵⁹—only then can a drug company submit a New Drug Application (NDA), a formal request to the FDA seeking approval of the drug to be marketed in the United States. After an NDA is received, the FDA has sixty days to determine whether to file the application for comprehensive review.⁶⁰ All in all, the entire drug approval process can take over a decade to complete and cost pharmaceutical companies approximately \$1.2 billion per drug.⁶¹

⁵⁴ *Id.*; see also FDCA § 505(a), 21 U.S.C. § 355(a).

⁵⁵ *IND Application*, *supra* note 52.

⁵⁶ *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA, <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm> [<https://perma.cc/RUZ2-K5FG>] (last updated Nov. 6, 2014) [hereinafter *Drug Review Process*].

⁵⁷ *Id.*

⁵⁸ See generally FDCA § 505(b), 21 U.S.C. § 355(b). Phase I studies typically consist of twenty to eighty healthy individuals, and the goal of this initial phase is to determine whether a drug is safe, its most frequent side effects, and how it is metabolized and excreted. 21 C.F.R. § 312.21(a) (2015); *Drug Review Process*, *supra* note 56. If the results of Phase I studies do not reveal excessive toxicity, Phase II studies begin. Approximately seventy percent of drugs successfully pass Phase I. Dresser, *supra* note 5, at 1634. While the emphasis in Phase I is safety, Phase II addresses a drug's efficacy. At this stage, there are typically between a few dozen and 300 participants who all have a common disease—some are given the experimental drug and other patients receive a placebo. *Drug Review Process*, *supra* note 56. The purpose of Phase II studies is to “evaluate the effectiveness of the [Phase I investigational new] drug . . . and to determine the common short-term side effects and risks associated with the drug.” 21 C.F.R. § 312.21(b). Only about one third of proposed drugs are successful at both Phases I and II. Dresser, *supra* note 5, at 1635. Finally, if a drug shows promise of effectiveness at Phase II, Phase III testing expands the testing pool to between several hundred and 3,000 subjects and focuses on both safety and efficacy, administering the drug to different populations, in different dosages, and in combination with other drugs. *Drug Approval Process Infographic*, FDA, <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> [<https://perma.cc/89SU-D4DJ>]; see also 21 C.F.R. § 312.21(c).

⁵⁹ *The Drug Development Process: Step 3: Clinical Research*, FDA, <http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm> [<https://perma.cc/29TT-XWHT>] (last updated Nov. 23, 2015).

⁶⁰ *Drug Approval Process Infographic*, *supra* note 58.

⁶¹ Leonard, *supra* note 15.

Given the time and cost associated with the FDA approval process, the FDCA also provides options for manufacturers to apply for expedited approval of a drug if certain additional criteria are met.⁶² For example, a drug can receive a “Fast Track” designation if it will be used to treat a serious condition and has the potential to address an unmet medical need.⁶³ Such a classification may make a manufacturer eligible for “rolling review,” whereby the Agency agrees to review portions of the NDA prior to the sponsor submitting a completed application.⁶⁴ If a drug is approved via this process, the Agency may require the sponsor to conduct post-approval studies.⁶⁵ In addition, the Accelerated Approval program provides another expedited route to drug approval through the utilization of surrogate endpoints.⁶⁶ Rather than waiting an extended time to determine whether a drug provides an intended clinical benefit, the FDA can base its approval of drugs on the use of surrogate endpoints, which are markers—such as a laboratory measure or an X-ray—that predict a likely clinical benefit.⁶⁷ For example, many cancer drugs proceed via the Accelerated Approval program. Rather than waiting to see whether a cancer drug will in fact extend human life, the FDA may approve a drug based on evidence that it shrinks a tumor, as such evidence serves as a surrogate endpoint and is considered predictive of extending life expectancy.⁶⁸

3. *Expanded Access: Compassionate Use*

In addition to the Fast Track and Accelerated Approval programs designed to expedite approval of NDAs, the FDA also provides avenues for individuals to gain access to drugs that have not yet been approved via either the traditional or expedited processes. Under its compassionate use program, the FDA allows drug companies to manufacture and distribute individual dosages of unapproved, investigational drugs to certain qualifying individuals.⁶⁹ The aim of this program is to “facilitate the availability of [investigational] drugs to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient’s disease or condition.”⁷⁰

⁶² 21 C.F.R. § 312.80; *see also* FDA, GUIDANCE FOR INDUSTRY: EXPEDITED PROGRAMS FOR SERIOUS CONDITIONS—DRUGS AND BIOLOGICS 1 (May 2014) [hereinafter FDA GUIDANCE: EXPEDITED PROGRAMS], <http://www.fda.gov/downloads/drugs/guidance/complianceregulatoryinformation/guidances/ucm358301.pdf> [<https://perma.cc/63HX-X2S3>].

⁶³ FDCA § 506, 21 U.S.C. § 356; *see also* FDA GUIDANCE, *supra* note 62, at 9.

⁶⁴ FDA GUIDANCE, *supra* note 62, at 10.

⁶⁵ FDCA § 506, 21 U.S.C. § 356.

⁶⁶ *See* 21 C.F.R. § 314.500.

⁶⁷ *Drug Approval Process Infographic*, *supra* note 58.

⁶⁸ *Id.*

⁶⁹ *See generally* Information for Patients, *supra* note 19.

⁷⁰ 21 C.F.R. § 312.300(a); *New HIV/AIDS Therapies*, *supra* note 20. “Serious disease or condition” is defined in the regulation as “a disease or condition associated with

In order for an individual to qualify for compassionate use, a sponsor must submit an IND application or protocol amendment to an existing IND on her behalf.⁷¹ This application is typically submitted by an individual's physician and is estimated to take approximately 100 hours to complete.⁷² Moreover, a physician must also make an independent determination that the "probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition," and the FDA must be satisfied that "the patient cannot obtain the drug under another IND or protocol."⁷³ Finally, prior to completing the application, the patient and physician must have first obtained consent from a drug manufacturer willing to provide the experimental drug.

If a new IND is submitted, the FDA has thirty days to consider it before either granting or denying access.⁷⁴ If a new protocol is submitted as an amendment to an existing IND, there is no thirty-day wait period; however, the protocol must be received by the FDA and approved by an IRB before treatment may begin.⁷⁵ If access is granted, the regulations stipulate monitoring and reporting requirements for the treating physician, including the submission of reports relating to safety and adverse events.⁷⁶

morbidity that has [a] substantial impact on day-to-day functioning." 21 C.F.R. § 312.300(b).

⁷¹ 21 C.F.R. § 312.305(b).

⁷² *Id.* Some of the requirements of the application are listed below:

- (ii) The rationale for the intended use of the drug, including [all] of [the] available therapeutic options that would ordinarily be tried before resorting to the investigational [new] drug or an explanation of why the use of the investigational [new] drug is preferable to the use of available therapeutic options;
- (iii) . . . [A] description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition;
- (iv) The method of administration of the drug, dose, and duration of therapy;
- (v) A description of the facility where the drug will be manufactured;
- (vi) Chemistry, manufacturing, and controls information . . . ;
- (vii) Pharmacology and toxicology information . . . ;
- (viii) A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks.

Id.

⁷³ *Id.* § 312.310(a)(1)–(2).

⁷⁴ *Id.* § 312.305(d).

⁷⁵ *Expanded Access Categories for Drugs (Including Biologics)*, FDA, <http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/cm431774.htm> [<https://perma.cc/UXH7-QD6H>] (last updated Feb. 4, 2015).

⁷⁶ 21 C.F.R. § 312.310(c). The FDA also offers "emergency expanded access" if an emergency requires that a patient be treated before the written application can be completed. Under this exception, the treating physician can request access by making a phone call to the FDA and explaining how the expanded access, if granted, will meet all regulatory requirements of sections 312.305 and 312.310. A written application must then be submitted within fifteen working days. *Id.* § 312.310(d).

B. *Obstacles to Access for Terminally Ill Individuals Under the FDA System*

Thus, under current FDA protocol, an individual with a terminal illness seeking to gain access to unapproved treatment, has three options: (1) Wait until the drug is granted FDA-approval via the traditional or Fast Track processes; (2) Apply to be a participant in a clinical trial currently underway by drug manufacturers working towards FDA approval; or (3) Apply to the FDA’s compassionate use program.

Because drug approval can take upwards of a decade, and time is not a luxury terminally ill patients enjoy, the first option is not a viable one. Applying and being accepted into a clinical trial is ideal, as a patient gains immediate access to treatment and is closely monitored by scientists and physicians. However, the terminally ill oftentimes fail to meet specific eligibility requirements for clinical trials as their conditions may be too complex and advanced. Such complexity makes it difficult for scientists to control for certain variables and isolate the single condition that the drug is supposed to treat, ultimately hindering their ability to properly assess a drug’s safety and effectiveness.⁷⁷ Furthermore, some patients may live too far away from clinical trials to participate, or their age or exposure to previous treatments may make them ineligible; still others may not even apply for such trials due to an unwillingness to accept frequent testing demands or out of fear of being given a placebo.⁷⁸

Because many individuals will be turned away from clinical trials, expanded access is often their final hope. Unfortunately, while the FDA’s compassionate use program allows terminally ill patients the opportunity to gain access to a drug without having to wait years until it is approved, this expedited process may still take a significant amount of time to complete. Physicians seeking experimental treatment on behalf of a terminally ill individual must first obtain manufacturer consent and IRB approval, and complete dense and complex paperwork before the FDA will review the case.⁷⁹ And even then, in certain instances after submission of the application, the FDA has at least thirty days to make a determination as to whether or not to grant access.⁸⁰

While the FDA has purportedly approved ninety-nine percent of compassionate use requests between 2010 and 2014, critics complain that this approval rate only accounts for a fraction of the total patients who might possibly benefit from experimental treatments, excluding those who either didn’t know about expanded access or who had a doctor with insufficient time

⁷⁷ Leonard, *supra* note 15.

⁷⁸ Dresser, *supra* note 5, at 1635–36.

⁷⁹ See *supra* Part II.A.3; see also Leonard, *supra* note 15.

⁸⁰ 21 C.F.R. § 312.305(d).

to complete the paperwork.⁸¹ Because many believed the FDA treatment options for terminally ill individuals were inadequate, advocates of increased access turned first to the court system for redress, before lobbying state legislatures in what ultimately would lead to the passage of the first Right to Try laws.

C. Abigail Alliance and the Origin of Right to Try Laws

The foundation of the Right to Try laws can be traced back to Abigail Burroughs and a series of *Abigail Alliance* court decisions.⁸² Abigail Alliance for Better Access to Developmental Drugs (Alliance) is a public interest organization comprised of terminally ill patients and supporters seeking access to experimental drugs for the terminally ill.⁸³ The organization was founded by Frank Burroughs, whose daughter Abigail had been diagnosed with head and neck cancer when she was a student at the University of Virginia.⁸⁴ Abigail attempted to gain access to multiple experimental drugs that were undergoing clinical trials at the time, but failed to qualify for any of the studies.⁸⁵ Moreover, Abigail tried and failed to obtain access to treatment through the FDA's expanded access program because she was unable to obtain consent from a manufacturer to provide the drugs.⁸⁶

After Abigail's death in 2001, her father, Frank, founded the Alliance, which filed a citizen petition with the FDA.⁸⁷ This petition emphasized that there is a "different risk-benefit tradeoff facing patients who are terminally ill and who have no other treatment options," and urged that terminally ill patients should be given the opportunity to try new treatments that have met a lower evidentiary burden in regards to their safety and efficacy.⁸⁸

⁸¹ Lisa Rapaport, *U.S. 'Right to Try' Laws May Not Help Dying Get Unapproved Drugs*, REUTERS (Sept. 28, 2015), <http://www.reuters.com/article/us-health-dying-experimental-drugs-idUSKCN0RS2LN20150928> [<https://perma.cc/G5UH-GF6X>]; see also The Editorial Bd., *FDA vs. Right to Try: Our View*, USA TODAY (Aug. 17, 2014), <http://www.usatoday.com/story/opinion/2014/08/17/ebola-drugs-terminally-ill-right-to-try-editorials-debates/14206039/> [<https://perma.cc/GCL2-GMQE>] (recognizing that the process to obtain experimental treatment is so daunting that fewer than 1,000 people sought and received federal approval in 2014).

⁸² Jann Bellamy, *The Illusions of "Right to Try" Laws*, SCI-BASED MED. (Mar. 6, 2014), <http://www.sciencebasedmedicine.org/the-illusions-of-right-to-try-laws/> [<https://perma.cc/8NLN-HD8U>].

⁸³ *Abigail All. for Better Access to Developmental Drugs v. von Eschenbach (Alliance II)*, 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc), rev'g 445 F.3d 470 (D.C. Cir. 2006).

⁸⁴ See Jerry Menikoff, *Beyond Abigail Alliance: The Reality Behind the Right to Get Experimental Drugs*, 56 KAN. L. REV. 1045, 1050 (2008).

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Alliance II*, 495 F.3d at 699 (quoting Citizen Petition of the Abigail Alliance & the Washington Legal Foundation to the Food & Drug Administration at 9, *In re Tier 1 Initial*

The FDA did not respond to this petition, and the Alliance resorted to filing a claim in federal court, appending a constitutional argument as well.⁸⁹ The Alliance argued that the Constitution provided a right of access to experimental drugs for the terminally ill, and that the FDA’s lengthy approval process, combined with numerous restrictions on preapproval availability, denied them this right and “amount[ed] to a death sentence for these [terminally ill] patients.”⁹⁰ The Alliance contended that this right of access should include allowing sponsors to market experimental drugs after the completion of Phase I trials.⁹¹

A panel of three on the D.C. Circuit found the Alliance’s claim to have merit and recognized the existence of a constitutional right of access; however, this decision was reversed en banc.⁹² The en banc court held that terminally ill patients do not have a fundamental right protected by the Due Process Clause to access investigational drugs.⁹³ The court reached this conclusion after determining that our nation has a history of federal drug regulation, emphasizing both the scope and purpose of the FDCA and the 1962 amendments thereto, which granted full authority to the FDA to condition a drug’s market approval on meeting safety and efficacy requirements.⁹⁴ Further, the court emphasized that although a drug may pass Phase I trials, this

Approval Program to Expedite the Availability of Lifesaving Drugs (June 11, 2003), <http://www.fda.gov/ohrms/dockets/dockets/03p0274/03p-0274-cp00001-01-vol1.pdf> [<https://perma.cc/8ZLB-7B5F>].

⁸⁹ *Id.* at 700. Although the FDA did not respond to this particular petition, it had responded to earlier petitions by the Alliance, where it noted that the issues raised pointed to “an area of significant range of opinion within the patient and provider communities about the standards that should be met before a drug is marketed.” *Id.* (quoting Letter from Peter J. Pitts, Assoc. Comm’r for External Relations, Dep’t of Health & Human Servs., to Frank Burroughs, President, Abigail All. for Better Access to Developmental Drugs 4 (Apr. 25, 2003) [hereinafter DHHS Letter]). The FDA also commented on the inevitable tension between early availability of these products and the need to obtain sufficient data as to their safety and efficacy. Ultimately, the Agency concluded that accepting Alliance’s proposal “would upset the appropriate balance that [it is] seeking to maintain, by giving almost total weight to the goal of early availability and giving little recognition to the importance of marketing drugs with reasonable knowledge for patients and physicians of their likely clinical benefit and their toxicity.” *Id.* (alteration in original) (quoting DHHS Letter, *supra*, at 5).

⁹⁰ *Id.* (second alteration in original) (quoting Complaint ¶ 14, Abigail All. for Better Access to Development Drugs v. McClellan, No. 03-1601, 2004 WL 3777340 (D.D.C. Aug. 30, 2004)).

⁹¹ *Id.* at 701.

⁹² *Id.* at 697.

⁹³ *Id.*

⁹⁴ *Alliance II*, 495 F.3d at 705–06 (“The fact that a drug has emerged from Phase I with a determination that it is safe for limited clinical testing in a controlled and closely-monitored environment after detailed scrutiny of each trial participant does not mean that a drug is safe for use beyond supervised trials. FDA regulation of post-Phase I drugs is entirely consistent with our historical tradition of prohibiting the sale of unsafe drugs.” (footnote omitted)).

does not amount to a determination that a drug is safe for general consumption: “current law bans access to an experimental drug on safety grounds until it has successfully completed all phases of testing.”⁹⁵

Interestingly, the opinion concluded by urging the Alliance to seek an alternative forum for its claims—the legislature.⁹⁶ The Alliance heeded the court’s advice, taking its arguments to state legislators who proved to be more receptive to its cause. Although a constitutional right would have recognized increased access nationwide, Right to Try laws ultimately seek to achieve the primary end goal of the Alliance—expanded access for terminally ill patients to experimental drugs—albeit one state at a time.

III. RIGHT TO TRY LEGISLATION

Within the past two years, Right to Try laws have emerged as an alluring alternative for terminally ill patients to the long and administratively arduous FDA drug approval process.⁹⁷ The main purpose of these state-based laws is to increase access to promising new drugs, allowing, as their name suggests, individuals with terminal illnesses the “right to try” experimental treatments that could potentially save their lives. State lawmakers seek to accomplish their goal of increased access by circumventing the protracted FDA approval process, thereby reducing paperwork, wait times, and overall federal administrative bureaucracy.⁹⁸ In states that have passed Right to Try laws,

⁹⁵ *Id.* at 703; *see also* 21 C.F.R. § 312.21(b) (2015).

⁹⁶ *Alliance II*, 495 F.3d at 713 (“The Alliance’s arguments about morality, quality of life, and acceptable levels of medical risk are certainly ones that can be aired in the democratic branches, without injecting the courts into unknown questions of science and medicine. Our Nation’s history and traditions have consistently demonstrated that the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology, and are entitled to deference in doing so. . . . Consistent with [Supreme Court] precedent, our holding today ensures that this debate among the Alliance, the FDA, the scientific and medical communities, and the public may continue through the democratic process.”).

⁹⁷ These laws were originally dubbed “Dallas Buyers Club” bills, a reference to the recent, award-winning movie that chronicled the story of an AIDS patient’s efforts to smuggle unapproved drugs from Mexico into Texas, in a desperate attempt to treat symptoms of the disease, while portraying the FDA as an indifferent and unresponsive bureaucracy. Dennis & Cha, *supra* note 27. Activists of the AIDS epidemic were largely responsible for the creation of the FDA’s first broad expanded access program, which made it easier for AIDS patients to obtain investigational drugs outside of clinical trials, which were difficult to qualify for. Dresser, *supra* note 5, at 1636. The association of Right to Try laws with this pop-culture film has been used as a springboard for legislators attempting to implement health policy and has been effective in capturing widespread public support.

⁹⁸ CHRISTINA CORIERI, GOLDWATER INST., POLICY REPORT NO. 266: EVERYONE DESERVES THE RIGHT TO TRY: EMPOWERING THE TERMINALLY ILL TO TAKE CONTROL OF THEIR TREATMENT 1 (Feb. 2014), https://goldwater-media.s3.amazonaws.com/cms_page_media/2015/1/28/Right%20To%20Try.pdf [<https://perma.cc/X7YS-T8PT>].

terminally ill patients are no longer required to wait for drugs to complete the FDA approval process—a delay many cannot afford—nor must their physicians navigate the bureaucratic thickets of the FDA’s compassionate use program in order to gain access to encouraging new treatment options.⁹⁹ The laws thereby eliminate the 100-hour FDA compassionate use application process, and doctors, on behalf of their patients, may work directly with drug manufacturers to discuss the benefits and risks of experimental treatment options and reach a final determination without involving the FDA.¹⁰⁰

The Goldwater Institute and the Alliance have been the leading advocates of Right to Try legislation and largely responsible for jumpstarting the conversation for expanded access for terminally ill individuals at the state level.¹⁰¹ Believing that the FDA should not inhibit individuals from exercising a basic freedom of preserving one’s own life, the Goldwater Institute encouraged states to pass legislation offering individuals a way to obtain investigational drugs that have passed certain basic safety testing, provided that a physician has recommended the treatment, the patient has provided informed consent, and the drug manufacturer has signaled a willingness to provide the drugs.¹⁰² The Goldwater Institute also provided template legislation for Right to Try laws,¹⁰³ which has been adopted by some states in its entirety.¹⁰⁴ Several key provisions of this model act are set forth below:

- To gain access to treatment, an individual must be an Eligible Patient, defined as someone with an Advanced Illness who has considered all other FDA-approved treatment options, received recommendation from her physician, given informed consent, and secured documentation from her physician that she meets the criteria of an Eligible Patient;¹⁰⁵
- Advanced Illness is defined as “a progressive disease or medical or surgical condition that entails significant functional impairment, that is not considered by a treating physician to be reversible even with administration of current federal drug administration approved and available treatments, and that, without life-sustaining procedures, will soon result in death;”¹⁰⁶
- Investigational Drugs eligible to be provided via Right to Try legislation are those drugs that have “successfully completed [a]

⁹⁹ Leonard, *supra* note 15.

¹⁰⁰ *Id.*; Dennis & Cha, *supra* note 27.

¹⁰¹ Leonard, *supra* note 15 (according to Darcy Olsen, President of the Goldwater Institute: “Terminal patients shouldn’t have to ask the government for permission to try to save their own lives.”); *see also infra* Part V.A.

¹⁰² CORIERI, *supra* note 98, at 1.

¹⁰³ Right to Try Model Legislation, *supra* note 15.

¹⁰⁴ *See, e.g.*, Right to Try Act, 2014 Mich. Legis. Serv. P.A. 345 (S.B. 991) (codified at MICH. COMP. LAWS ANN. §§ 333.26451–.26457 (West Supp. 2015)).

¹⁰⁵ Right to Try Model Legislation, *supra* note 15, § 1(2)(b).

¹⁰⁶ *Id.* § 1(2)(a).

Phase 1 . . . clinical trial” and, while not yet approved for general use by the FDA, continue to undergo further FDA-approved clinical trial testing.¹⁰⁷

- Neither insurance providers nor drug manufacturers are obligated to pay for the care and treatment costs that result from the use of the investigational drug or treatment, and consequently, the Eligible Patient may be liable for all expenses related to the experimental treatment,¹⁰⁸ and
- Doctors, hospitals, and manufacturers that do not follow the FDA approval process are protected from disciplinary actions taken by a licensing board or disciplinary subcommittee.¹⁰⁹

The first wave of Right to Try legislation took hold in 2014 when five states enacted such laws—Colorado,¹¹⁰ Louisiana,¹¹¹ Missouri,¹¹² Michigan,¹¹³ and Arizona.¹¹⁴ These laws continued to gain momentum at a dramatic pace in 2015, as now over twenty states have passed some version of

¹⁰⁷ *Id.* § 1(2)(c).

¹⁰⁸ *Id.* §§ 1–3.

¹⁰⁹ *Id.* §§ 1–3, 5; *see also* Leonard, *supra* note 15. It is important to note, however, that these laws may only protect such parties from prosecution at the state level. The FDA still holds federal jurisdiction and therefore these parties will likely not be protected from all liability. Furthermore, regardless of the overall legality of these laws, the ability of a state to prevent liability from befalling a party when there is diversity jurisdiction (e.g., when a doctor requests medication from a drug maker in another state) seems unlikely.

¹¹⁰ Right To Try Act, 2014 Colo. Legis. Serv. Ch. 220 (H.B. 14-1281) (codified at COLO. REV. STAT. §§ 25-45-101 to -108 (2015)). The first amongst Right to Try laws, this bill was passed unanimously by the Colorado legislature in May 2014. While the law does not explicitly follow the Goldwater legislation, it does draw heavily from its text. Representative Joann Ginal, a co-sponsor of the bill, was inspired after an experimental treatment helped her older brother who had been diagnosed with a rare blood cancer. Dennis & Cha, *supra* note 27.

¹¹¹ Right to Try Act, 2014 La. Sess. Law Serv. Act 346 (H.B. 891) (codified at LA. STAT. ANN. §§ 40:1169.1–.6 (Supp. 2016)). Passed on the heels of Colorado’s law, the Louisiana act closely parallels its sister state and also contains a section of legislative findings.

¹¹² 2014 Mo. Legis. Serv. H.B. 1685 (codified at MO. ANN. STAT. § 191.480 (West Supp. 2015)). In July 2014, Missouri became the third state to pass a Right to Try law. State Representative Jim Neely, a physician, was the sponsor of the bill. His daughter has been battling colon cancer and has been disqualified from participating in clinical trials to receive access to investigational treatment. Mike Sherry, *Missouri Becomes Third State to Enact ‘Right to Try’ Drug Therapy Law*, KCPT (July 15, 2014), <http://www.kcpt.org/health/missouri-state-enact-right-try-drug-therapy-law> [<https://perma.cc/FD5W-FWUE>].

¹¹³ Right to Try Act, 2014 Mich. Legis. Serv. P.A. 345 (S.B. 991) (codified at MICH. COMP. LAWS ANN. §§ 333.26451–.26457 (West Supp. 2015)). Passed in October 2014, this law is identical to the Goldwater Institute model legislation.

¹¹⁴ Terminal Patients’ Right to Try Act, 2014 Ariz. Legis. Serv. H. Con. Res. 2005 (codified at ARIZ. REV. STAT. ANN. §§ 36-1311 to -1314 (West Supp. 2015)). Arizona became the first state to pass a Right to Try law by ballot initiative in November 2014.

Right to Try legislation.¹¹⁵ This phenomenon will likely continue as many more states have bills currently pending.¹¹⁶ The majority of Right to Try laws that have been enacted have garnered bipartisan support and have passed unanimously in state legislatures across the country.¹¹⁷ In October 2015, however, Governor Jerry Brown became the first governor to veto a Right to Try bill, despite the fact that it passed the California State Assembly by a unanimous vote.¹¹⁸ The Governor cited recent FDA reform measures that attempt to streamline the compassionate use program as the reason for the

¹¹⁵Gabe Griffin Right to Try Act, 2015 Ala. Laws Act 2015-320 (S.B. 357) (codified at ALA. CODE §§ 22-5D-1 to -10 (LexisNexis 2015)); Terminal Patients’ Right to Try Act, 2014 Ariz. Legis. Serv. H. Con. Res. 2005 (codified at ARIZ. REV. STAT. ANN. §§ 36-1311 to -1314 (West Supp. 2015)); Right to Try Act, 2015 Ark. Laws Act 374 (S.B. 4) (codified at ARK. CODE ANN. §§ 20-15-2101 to -2111 (Supp. 2015)); Right To Try Act, 2014 Colo. Legis. Serv. Ch. 220 (H.B. 14-1281) (codified at COLO. REV. STAT. §§ 25-45-101 to -108 (2015)); Right to Try Act, 2015 Fla. Sess. Law Serv. Ch. 2015-107 (H.B. 269) (codified at FLA. STAT. ANN. § 499.0295 (West Supp. 2016)); 2015 Ind. Legis. Serv. P.L. 2-2015 (H.E.A. 1065) (codified at IND. CODE ANN. §§ 16-42-26-1 to -5 (West Supp. 2015)); Right to Try Act, 2014 La. Sess. Law Serv. Act 346 (H.B. 891) (codified at LA. STAT. ANN. §§ 40:1169.1–.6 (Supp. 2016)); Right To Try Act, 2014 Mich. Legis. Serv. P.A. 345 (S.B. 991) (codified at MICH. COMP. LAWS ANN. §§ 333.26451–.26457 (West Supp. 2015)); Right to Try Act, 2015 Minn. Sess. Law Serv. Ch. 15 (S.F. 100) (codified at MINN. STAT. § 151.375 (2015)); Right to Try Act, 2015 Miss. Laws Ch. 423 (S.B. 2485) (codified at MISS. CODE ANN. § 41-131-1 (West Supp. 2015)); 2014 Mo. Legis. Serv. H.B. 1685 (codified at MO. ANN. STAT. § 191.480 (West Supp. 2015)); Right to Try Act, 2015 Mont. Laws Ch. 135 (S.B. 142) (codified at MONT. CODE ANN. §§ 50-12-101 to -110 (2015)); 2015 Nev. Laws Ch. 210 (A.B. 164, 2015 Leg., 78th Reg. Sess. (Nev. 2015)); Right to Try Act, 2015 N.C. Laws S.L. 2015-137 (H.B. 652) (codified at N.C. GEN. STAT. §§ 90-325 to -325.7 (2015)); 2015 N.D. Laws Ch. 199 (S.B. 2259) (codified at N.D. CENT. CODE §§ 23-48-01 to -05 (Supp. 2015)); Right to Try Act, 2015 Okla. Sess. Law Serv. Ch. 112 (H.B. 1074) (codified at OKLA. STAT. ANN. tit. 63, §§ 3091.1–.7 (West Supp. 2016)); 2015 S.D. Laws Ch. 188 (H.B. 1080) (codified at S.D. CODIFIED LAWS §§ 34-51-1 to -10 (Supp. 2015)); Phil Timp-Amanda Wilcox Right to Try Act, 2015 Tenn. Laws Pub. Ch. 376 (H.B. 143) (codified at TENN. CODE ANN. §§ 63-6-301 to -310 (Supp. 2015)); Right to Try Act, Tex. Sess. Law Serv. Ch. 502 (H.B. 21) (codified at TEX. HEALTH & SAFETY CODE ANN. §§ 489.001–.151 (West Supp. 2015)); Utah Right to Try Act, 2015 Utah Laws Ch. 110 (H.B. 94) (codified at UTAH CODE ANN. §§ 58-85-101 to -105 (LexisNexis Supp. 2015)); 2015 Va. Laws Ch. 655 (S.B. 732), Ch. 656 (H.B. 1750) (codified at VA. CODE ANN. §§ 54.1-3442.1 to -3442.4 (Supp. 2015)); Right to Try Act, 2015 Wyo. Laws Ch. 174 (S.F. 3) (codified at WYO. STAT. ANN. §§ 35-7-1801 to -1806 (2015)).

¹¹⁶See, e.g., An Act Providing a Right to Try, H.B. 3270, 189th Gen. Court, Reg. Sess. (Mass. 2015) (referred to Joint Committee on Public Health); Right to Try Act, S.B. 0029, 99th Gen. Assemb., Reg. Sess. (Ill. 2015) (final action deadline extended to April 2016).

¹¹⁷Michael Barone, *The Success of Right to Try Laws Signals a Major Policy Shift*, N.Y. POST (Oct. 6, 2015), <http://nypost.com/2015/10/06/the-success-of-right-to-try-laws-signals-a-major-policy-shift/> [<https://perma.cc/4MLG-4Z6B>].

¹¹⁸Laura Mahoney, *California Governor Vetoes Right-to-Try Bill*, BLOOMBERG BNA (Oct. 15, 2015), <http://www.bna.com/california-governor-vetoes-n57982059470/> [<https://perma.cc/X238-RW5C>].

veto.¹¹⁹ It is possible that the state legislature will override Governor Brown's veto in 2016, and it remains to be seen whether other states with pending legislation will follow the Governor's lead in taking a "wait and see" approach that would allow time for the FDA to implement new reforms.¹²⁰

IV. THE LEGAL DEBATE: ARE RIGHT TO TRY LAWS CONSTITUTIONAL?

Right to Try laws are unconstitutional because they are preempted by federal FDA authority. The FDCA creates a comprehensive statutory scheme of federal regulation in the approval, administration, labeling, and reporting requirements of drugs shipped in interstate commerce, and vests the FDA with exclusive authority to promulgate regulations in the area; consequently, state laws infringing on that exclusivity are null.¹²¹ Right to Try legislation itself explicitly recognizes the supremacy of federal law, noting that drugs administered via the state laws must not only pass Phase I clinical trials but also must *still be involved in the clinical trial process*.¹²² Once the FDA approval process commences, the manufacturer is by definition under FDA jurisdiction and thus bound to follow federal law.¹²³ However, because Right to Try laws directly conflict with the FDCA, it is impossible for a drug manufacturer to comply with both; thus, the law of preemption dictates that state law must cede to its federal counterpart.¹²⁴

A. *The Law of Preemption*

The concept of federal preemption derives its authority from the Supremacy Clause of the United States Constitution.¹²⁵ Based upon the language of this constitutional provision, it is well understood that state law

¹¹⁹ *Id.* ("Before authorizing an alternative state pathway, we should give this federal expedited process a chance to work." (quoting California Governor Jerry Brown in his veto message)). As an interesting juxtaposition, while vetoing the Right to Try bill, in 2015 Governor Brown signed into law a bill recognizing patients' "Right to Die." See George Skelton, *Gov. Brown Shows His Contrarian Side in Bills He Signed and Vetoed*, L.A. TIMES (Oct. 15, 2015), <http://www.latimes.com/local/politics/la-me-cap-brown-bills-20151015-column.html> [<https://perma.cc/8HLN-2HF8>].

¹²⁰ See *infra* Part VI.C for additional discussion on the FDA's latest efforts to reform its drug approval process.

¹²¹ Bellamy, *supra* note 82. Hypothetically, if a drug manufacturer operated completely intrastate, it is possible it would be immune from federal jurisdiction and not governed by the FDA.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.").

that contravenes federal law is “without effect.”¹²⁶ Moreover, the Supreme Court has indicated that the phrase “Laws of the United States” encompasses both federal statutes as well as “federal regulations that are properly adopted in accordance with statutory authorization.”¹²⁷

The Supreme Court has recognized two cornerstones of preemption jurisprudence. First, “the purpose of Congress is the ultimate touchstone in every pre-emption case.”¹²⁸ And second, when Congress has “‘legislated . . . in a field which the States have traditionally occupied,’ . . . [courts] ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’”¹²⁹ This presumption against preemption has particular force in matters affecting health and safety, which have historically been regarded as matters best left to the states for regulation.¹³⁰ However, the Supreme Court has indicated that this presumption does not apply to those interests at stake that are “uniquely federal” in nature.¹³¹ Instead, when the interest affects “[t]he relationship between a federal agency and the entity it regulates,” the relationship is “inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.”¹³²

There are two broad categories of preemption, express preemption and implied preemption.¹³³ A state law is expressly preempted when a federal statute explicitly states Congress’s intent to preempt state law.¹³⁴ Courts have been much more willing to invoke this type of preemption and have construed

¹²⁶ *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981); *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819).

¹²⁷ *City of New York v. FCC*, 486 U.S. 57, 63–64 (1988) (concluding that “‘a federal agency acting within the scope of its congressionally delegated authority may pre-empt state regulation’ and hence render unenforceable state or local laws that are otherwise not inconsistent with federal law” (quoting *La. Pub. Serv. Comm’n v. FCC*, 476 U.S. 355, 369 (1986))).

¹²⁸ *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

¹²⁹ *Id.* (alterations in original) (quoting *Lohr*, 518 U.S. at 485); *see also* *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518 (1992).

¹³⁰ *Lohr*, 518 U.S. at 485.

¹³¹ *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347 (2001) (quoting *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504 (1988)) (finding that “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied’” (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))); *see also* *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 378 (5th Cir. 2012) (noting that the Court has recently cast doubt on the presumption against preemption, specifically within the context of implied conflict preemption analysis).

¹³² *Buckman*, 531 U.S. at 347.

¹³³ *See Cipollone*, 505 U.S. at 516 (“Congress’ intent may be ‘explicitly stated in the statute’s language or implicitly contained in its structure and purpose.’” (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977))).

¹³⁴ *Lefavre v. KV Pharm. Co.*, 636 F.3d 935, 939 (8th Cir. 2011).

words in federal statutes that prohibit states from imposing “different or additional requirements” very liberally and broadly. However, the presence of an express preemption clause in a federal statute does not completely end the inquiry; the courts must still ascertain “the substance and scope” of Congress’s displacement of state law.¹³⁵

Implied preemption is further broken down into several subcategories. First, in what is known as field preemption, a federal law preempts a corresponding state law if the former so “thoroughly occupies a legislative field ‘as to make reasonable the inference that Congress left no room for the States to supplement it.’”¹³⁶ In determining whether the field is fully occupied, courts are to look to the pervasiveness of the federal scheme of regulation, the federal interest at stake, and the danger of frustration of federal goals.¹³⁷

Conflict preemption occurs when “[i]n the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law.”¹³⁸ There are two types of conflict preemption: impossibility preemption and obstacle preemption.¹³⁹ Impossibility preemption “arises when ‘compliance with both federal and state regulations is a physical impossibility.’”¹⁴⁰ Finally, obstacle preemption exists “when a state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”¹⁴¹

B. Right to Try Laws Within the Context of Preemption

Foremost, Right to Try laws do not present an issue of express preemption, as the FDCA contains no express preemption clause, unlike the MDA, where 21 U.S.C. § 360k states that “no State . . . may establish . . . any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device, and . . . which relates to the safety or effectiveness of the device.”¹⁴² To the contrary, the Kefauver Harris

¹³⁵ *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008).

¹³⁶ *Cipollone*, 505 U.S. at 516 (quoting *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982)); see also *Pennsylvania v. Nelson*, 350 U.S. 497, 504 (1956); *Rice*, 331 U.S. at 230.

¹³⁷ *Nelson*, 350 U.S. at 504 (“When Congress has taken the particular subject-matter in hand coincidence is as ineffective as opposition, and a state law is not to be declared a help because it attempts to go farther than Congress has seen fit to go.” (quoting *Charleston & W. Carolina Ry. v. Varnville Furniture Co.*, 237 U.S. 597, 604 (1915))).

¹³⁸ *Cipollone*, 505 U.S. at 516.

¹³⁹ *Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 605 (1991).

¹⁴⁰ *Id.* (quoting *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)).

¹⁴¹ *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

¹⁴² MDA § 2, 21 U.S.C. § 360k(a) (2012). When Congress included this express preemption provision within the MDA of 1976, it could have easily added a parallel provision for prescription drugs, yet declined to do so. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008).

Amendments to the FDCA added a savings clause to the Act, noting that “[n]othing in the amendments made by this Act to the [FDCA] shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments *unless there is a direct and positive conflict between such amendments and such provision of State law.*”¹⁴³ Therefore, it must be determined whether Right to Try laws are impliedly preempted, such that they create “a direct and positive conflict” with the FDCA.

In analyzing claims of implied preemption, the inquiry into congressional intent and purpose in enacting the FDCA is initially complicated when viewed within the context of the presumption against preemption.¹⁴⁴ There is a tension that, on the one hand, Congress may have chosen not to preempt state law because matters of health and safety have traditionally been left to states, yet on the other hand, Congress’s legislation in the field is so pervasive, or creates a direct conflict, such that there is no room for complementary state laws. However, this tension can be dispelled because Right to Try laws fundamentally alter the relationship between the FDA and drug manufacturers. By purporting to give manufacturers the go-ahead to provide experimental drugs without FDA approval, the interest at stake, the regulation of the drug approval process, is “uniquely federal,” and thus the presumption against preemption should not apply within the Right to Try context.

Therefore, in seeking to determine whether state Right to Try laws are impliedly preempted by FDA authority, it is appropriate to first look to the text of the FDCA and any accompanying FDA regulations, from which, taken together or individually, it can be gleaned Congress’s ultimate objective.¹⁴⁵ 21 U.S.C. § 355(a) is an appropriate starting point. This provision states that “[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.”¹⁴⁶ Subsection (b) governs the standard drug approval process, while subsection (j) discusses abbreviated new drug applications.¹⁴⁷ Right to Try laws seemingly grant drug manufacturers the right to deliver new drugs into interstate commerce so long as they have passed Phase I trials and remain in the clinical trial process, despite the absence of any form of FDA approval.

¹⁴³ Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962) (emphasis added).

¹⁴⁴ *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 621 F.3d 781, 792 (8th Cir. 2010) (“[I]t is often a perplexing question whether Congress has precluded state action or by the choice of selective regulatory measures has left the police power of the States undisturbed except as the state and federal regulations collide.” (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230–31 (1947))).

¹⁴⁵ *Reid v. Johnson & Johnson*, 780 F.3d 952, 959 (9th Cir. 2015); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 339–40 (3d Cir. 2009).

¹⁴⁶ FDCA § 505(a), 21 U.S.C. § 355(a) (2012).

¹⁴⁷ FDCA § 505(b), (j), 21 U.S.C. § 355(b), (j).

In addition, 21 U.S.C. § 356 of the FDCA and accompanying FDA regulations provide numerous ways for drug manufacturers to provide, and individual patients to obtain access to, unapproved drugs through the Agency's expedited drug approval process.¹⁴⁸ This comprehensive system provides strong indication that Congress did not intend for states to provide an alternate route to increased access of unapproved drugs.

Within the context of field preemption, the Supreme Court discussed at length in *Wyeth v. Levine* Congress's activity since 1906 in passing a series of federal statutes pertaining to drug and medical device regulation, including the FDCA in 1938 and MDA in 1976.¹⁴⁹ In *Wyeth*, the question was whether the FDA's drug labeling judgments preempted state law product liability claims.¹⁵⁰ The Court concluded that Congress had ample opportunity to include an express preemption provision in the FDCA within the FDA's seventy-year history, yet chose not to do so.¹⁵¹

Congressional silence on the issue, despite its awareness of the prevalence of tort litigation, coupled with the fact that Congress *did* include an express preemption provision for medical devices in 1976, was powerful indication that Congress regarded state law product liability claims as a complementary form of drug regulation.¹⁵² Because the "FDA has [only] limited resources to monitor the 11,000 drugs on the market," the Agency has "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation."¹⁵³

While the FDA does not necessarily "occupy the field" of drug regulation, Right to Try laws likely do not serve as a form of complementary regulation that the Supreme Court had in mind in *Wyeth*. Historically, the FDA looked to states to offer *additional* forms of drug regulation, such as through common law torts of failure to warn and product liability claims;¹⁵⁴ Right to Try laws, however, *remove* safeguards governing the accessibility of drugs by

¹⁴⁸ FDCA § 506, 21 U.S.C. § 356.

¹⁴⁹ See generally *Wyeth v. Levine*, 555 U.S. 555, 566–68 (2009) (discussing the history of the federal statutes relating to drug and medical device regulation).

¹⁵⁰ *Id.* at 558–59.

¹⁵¹ *Id.* at 574.

¹⁵² *Id.* at 578–79.

¹⁵³ *Id.*; *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) (noting that state tort suits "can serve as a catalyst" by aiding in the exposure of new dangers and prompting a manufacturer or the federal agency to decide that a revised label is required); *Lefaiivre v. KV Pharm. Co.*, 636 F.3d 935, 941 (8th Cir. 2011) (concluding that the "'federal statutory or regulatory scheme' . . . is *not* 'so pervasive in scope that it occupies the field'" (quoting *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 621 F.3d 781, 792 (8th Cir. 2010))).

¹⁵⁴ *Wyeth*, 555 U.S. at 573–74. In *Wyeth*, the Court recognized that "Congress enacted the FDCA to bolster consumer protection against harmful products" and that state law remedies, such as the common law tort of failure to warn, may further Congress's purpose by providing another impetus for manufacturers "to produce safe and effective drugs and to give adequate warnings." *Id.* at 574.

circumventing the FDA altogether. Rather than increasing the level of assurance that drugs being used are safe and effective, Right to Try laws allow for individuals to receive experimental treatments without the knowledge of the FDA, consequentially undermining the Agency’s monitoring mechanism. This distinction would likely be important to a court because, despite whether there is room for federal and state drug regulation to coexist, the law of federal supremacy likely forestalls those state laws that weaken federal enforcement mechanisms.

Moreover, state Right to Try laws will almost certainly not pass muster under either type of conflict preemption. As to impossibility preemption, drug manufacturers physically cannot remain in compliance with the FDA if they provide drugs to patients under Right to Try laws. In *PLIVA v. Mensing*, the Court found it impossible for drug manufacturers to comply with both state tort law and federal drug labeling regulations.¹⁵⁵ New state law placed heightened requirements on drug manufacturers to adequately and safely label their products, which the plaintiffs in the case argued imposed stricter requirements than the FDA had imposed when the drug labels were approved initially.¹⁵⁶ The FDA, however, prevented the drug manufacturers from independently strengthening their labels to bring them in compliance with state law without first obtaining approval through its amendment process.¹⁵⁷ Thus, the Court concluded: “We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them.”¹⁵⁸

Likewise, it is “not lawful under federal law” for a drug manufacturer to provide a drug to a Right to Try patient that has only passed a Phase I clinical trial and has not been approved by the FDA for distribution under one of its expedited approval or expanded access programs. Therefore, like the Supreme Court found in *PLIVA*, a court would likely “find impossibility” where a drug manufacturer was required to comply with the FDA while simultaneously proceeding under contradictory Right to Try legislation.

Additionally, Right to Try legislation frustrates the FDA’s goal of ensuring that drugs are safe and effective, as the Agency no longer has the capability to monitor those drugs given to terminally ill patients via the state laws. Further, drug manufacturers may have increased difficulty finding enough individuals to participate in clinical trials, jeopardizing the ability of a drug to gain final FDA approval for general public consumption.

In *Buckman Co. v. Plaintiffs’ Legal Committee*, the Court found that state law tort claims against drug manufacturers alleging “fraud-on-the-FDA” posed a direct conflict “with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.”¹⁵⁹ Similarly, in the Right

¹⁵⁵ *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011).

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001); *see also* *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965–66 (6th Cir. 2004).

to Try context, the FDA is tasked with ensuring that drugs are safe and effective,¹⁶⁰ and by states creating laws allowing individuals to obtain drugs directly from manufacturers without FDA oversight, the FDA's ability to fulfill its mission is frustrated.

V. THE POLICY DEBATE: ARE RIGHT TO TRY LAWS EFFECTIVE?

Despite the fact that Right to Try laws, if challenged in court, will likely be found unconstitutional, the most extensive discussion currently surrounding the state laws is whether they are a good idea in terms of policy. There is an inherent tension between advocating for faster approval of drugs with the hopes of saving lives versus ensuring the drugs are adequately and rigorously tested so that they will be safe and effective when approved for general public consumption. Advocates of Right to Try legislation criticize the FDA's lengthy and cumbersome policies, especially as they apply to terminally ill individuals, and the government's over-involvement in patients' lives.¹⁶¹ Opponents of the laws underscore the concern that the laws are more symbolic than effective, could result in uncertainty and false hope, and threaten to undermine the drug development process as a whole.

A. *Advocates*

Frustration with the FDA's current drug approval and compassionate use programs unite advocates of Right to Try laws. They decry the current process to gain early access as archaic, lengthy, and cumbersome—especially when an individual's life is at stake.¹⁶² Led by the libertarian Goldwater Institute, they argue that the government is too involved in life-or-death decisions that should be between individual patients and physicians.¹⁶³ According to the Goldwater Institute's President, Darcy Olsen: "Americans deserve transparency. . . . They should not have to beg their government for the right to save their own lives, or stand by while the government makes decisions behind a veil of secrecy, (decisions) that allow some to live and leave others to die."¹⁶⁴ Right to Try laws enhance individual autonomy by "cut[ting] through [the] red tape" of bureaucracy and allowing doctors, on behalf of their patients, to negotiate directly with drug companies, eliminating the federal government from much of the process.¹⁶⁵

Moreover, Right to Try supporters underscore that the need for more streamlined access to experimental treatments is especially paramount for the

¹⁶⁰ See generally FDCA § 303, 21 U.S.C. § 393 (2012) (vesting the FDA's authority).

¹⁶¹ Dennis & Cha, *supra* note 27.

¹⁶² *Id.*

¹⁶³ CORIERI, *supra* note 98, at 1 ("For patients suffering from terminal illnesses, the FDA is the arbiter of life and death.").

¹⁶⁴ Barone, *supra* note 117 (quoting DARCY OLSEN, RIGHT TO TRY (2015)).

¹⁶⁵ Dennis & Cha, *supra* note 27.

terminally ill. Unfortunately, time is limited for these patients and none of the FDA processes offer meaningful pathways to access soon enough to make a difference in their lives; therefore, proponents of Right to Try laws believe that the unique circumstances surrounding patients eligible to receive treatment under these laws warrant an exception to bureaucratic treatment.¹⁶⁶ “It’s hard to argue that a terminally ill person is taking huge risks. . . . The drugs could make you die faster or make you miserable, but you’re already headed toward a bad outcome.”¹⁶⁷

According to Right to Try advocates, the opinion of a physician coupled with minimal safety testing is an adequate scientific basis to allow the terminally ill access to investigational drugs.¹⁶⁸ And even though Right to Try laws may not completely eliminate barriers to access, as patients will still need agreement from drug manufacturers to provide the drugs, they are an important first step. The laws eliminate 100 hours of FDA-required paperwork, allowing physicians to focus their time on negotiating access to the drugs for their patients. Finally, the short history of Right to Try laws demonstrate our Nation’s system of dual sovereignty operating at its finest: deterred in federal court, Right to Try supporters turned to the states as laboratories of democracy to garner support for their cause.¹⁶⁹ And regardless of whether Right to Try laws are ultimately utilized at the state level, they have been successful in sparking national discussion and spurring federal reform.¹⁷⁰

B. Critics

Despite the fact that most Right to Try laws passed to date have attracted widespread support, due in part to their strong emotional pull, the laws have not been without their fair share of critics, including science and policy experts who are united in opposition.

¹⁶⁶ Leonard, *supra* note 15 (“[L]ack of bureaucracy is needed when it’s literally a matter of life and death.”).

¹⁶⁷ *Id.* (quoting Arthur Caplan, Director of the Division of Medical Ethics in NYU Langone Medical Center’s Department of Population Health).

¹⁶⁸ Dresser, *supra* note 5, at 1631.

¹⁶⁹ Barone, *supra* note 117.

¹⁷⁰ See *infra* Part VI.C for discussion of the FDA’s compassionate use reform measures rolled out in February 2015 and a federal Right to Try bill that was recently re-introduced in Congress. Additionally, for a discussion as to how the recent Ebola outbreak may have positively affected the passage of Right to Try legislation, see Nick Gillespie, *The Upside of Ebola (Yes, There May Actually Be One)*, DAILY BEAST (Oct. 12, 2014), <http://www.thedailybeast.com/articles/2014/10/12/the-upside-of-ebola-yes-there-may-actually-be-one.html> [<https://perma.cc/FUM7-KREM>].

1. *Ineffective at Achieving Their Purpose*

Opponents characterize Right to Try laws as “nothing but feel-good placebos’ that will have no real impact on drug access.”¹⁷¹ The current bottleneck to access, they argue, is not the FDA, who approves ninety-nine percent of all compassionate use requests, but rather drug manufacturers who are unwilling to provide the drugs out of concerns for cost, liability, and fear of jeopardizing ultimate FDA approval. Yet Right to Try laws do nothing to incentivize manufacturers to provide the drugs.

For example, drug companies have expressed concern that by providing experimental drugs to Right to Try patients, they may jeopardize their chance at FDA authorization because they are circumventing the very Agency they seek ultimate approval from to market their drugs to the public.¹⁷² This could be the case if the experimental treatment exposes previously unknown health complications or is ineffective. Additionally, there is concern that drug companies could face federal liability should they provide drugs via the state laws, as the FDA could challenge the unauthorized distribution as a violation of the FDCA.¹⁷³

Furthermore, there is the problem of affordability. The production of new drugs is expensive and companies typically only produce the precise number of doses needed for clinical trials.¹⁷⁴ It may be unrealistic to believe that drug companies will provide experimental treatments free of charge, and insurance companies are not required under the state laws to cover the costs.¹⁷⁵ Because the laws do not place responsibility for payment on any one party, this creates uncertainty, and a likelihood that the patient may end up footing the bill,

¹⁷¹ Dresser, *supra* note 5, at 1641 (quoting David Gorski, “Right to Try” Laws and Dallas Buyers’ Club: Great Movie, Terrible for Patients and Terrible Policy, SCI.-BASED MED. (Mar. 8, 2014), <https://www.sciencebasedmedicine.org/right-to-try-laws-and-dallas-buyers-club-great-movie-terrible-public-policy/> [https://perma.cc/M8VY-XW7P]). Other critics warn that “[t]hese laws are easy to vote for but accomplish almost nothing,” and “are a simplistic way of going after much more complicated issues.” Leonard, *supra* note 15 (quoting Arthur Caplan, Director of the Division of Medical Ethics in NYU Langone Medical Center’s Department of Population Health, and R. Alta Charo, a professor of law and bioethics at the University of Wisconsin-Madison).

¹⁷² Dresser, *supra* note 5, at 1646–47.

¹⁷³ *Id.* Although Right to Try laws protect manufacturers from state liability, they can do nothing to prevent liability at the federal level.

¹⁷⁴ Ariana Eunjung Cha, *Crowdsourcing Medical Decisions: Ethicists Worry Josh Hardy Case May Set Bad Precedent*, WASH. POST (Mar. 23, 2014), https://www.washingtonpost.com/national/health-science/crowdsourcing-medical-decisions-ethicists-worry-josh-hardy-case-may-set-bad-precedent/2014/03/23/f8591446-ab81-11e3-adbc-888c8010c799_story.html [https://perma.cc/BCA9-DQRZ].

¹⁷⁵ See, e.g., Right to Try Model Legislation, *supra* note 15, § 3.

raising the potential to widen the gap of accessibility between the rich and the poor.¹⁷⁶

According to Sascha Haverfield, spokesperson for the pharmaceutical industry’s trade group, “[l]egislation at the state level, however well-intentioned, is unlikely to add any meaningful new approaches that can optimize the federal expanded access process overseen by [the] FDA.”¹⁷⁷ Corroborating this statement, there have been very few drug companies to date that have indicated a willingness to provide experimental drugs through the state legislation.¹⁷⁸ Thus, if the drug manufacturers are not on board with Right to Try legislation, the effectiveness of the laws will truly be limited.

2. Undermine Drug Development

Right to Try laws do not advance science and may in fact inhibit the FDA’s ability to monitor the success of experimental treatments, threatening the integrity of the drug approval process altogether.¹⁷⁹ Under current FDA regulations, doctors sponsoring patients proceeding under the compassionate use program are required to report any adverse events that result from the drug’s administration.¹⁸⁰ This oversight mechanism allows the FDA to harness its expertise in the drug development process;¹⁸¹ but because the FDA is not consulted under Right to Try laws, the Agency will be unable to track the success of experimental treatments provided at the state level.¹⁸²

In addition, the clinical trial process serves as an essential data-collecting tool for the Agency in determining whether drugs are safe and effective.¹⁸³

¹⁷⁶ Many Right to Try laws explicitly state that manufacturers may require the patient to cover cost of treatment and that insurance companies and governmental agencies are *not* required to provide coverage for the cost of the drugs. *See, e.g., id.* §§ 2(2), 3(2)–(3).

¹⁷⁷ Leonard, *supra* note 15. Haverfield went on to state the Pharmaceutical Research and Manufacturers of America “have serious concerns with any approach to make investigational medicines available that seeks to bypass the oversight of the Food and Drug Administration and clinical trial process, which is not in the best interest of patients and public health.” Ollove, *supra* note 1.

¹⁷⁸ *See* Sam Adriance, *Fighting for the “Right to Try” Unapproved Drugs: Law as Persuasion*, 124 YALE L.J. F. 148, 155 n.42 (2014). Ironically, the CEO of one of the few companies that has shown interest, Neuralstem, chairs the Goldwater Institute’s Right to Try Advisory Council. Even Neuralstem, though, who is developing an ALS drug, said it would ultimately defer to the FDA. *Id.*

¹⁷⁹ Leonard, *supra* note 15 (“You’d like to turn over every rock to make sure [someone] gets a chance to live, but from the standpoint of actually curing people [Right to Try laws are] not helpful. The most helpful thing we can do is to get the data . . . You don’t learn anything useful from the one-off cases.” (first and third alterations in original) (quoting Dr. Ezekiel Emanuel, Chair of the Department of Medical Ethics and Health Policy at the University of Pennsylvania)); *see also* Dennis & Cha, *supra* note 27.

¹⁸⁰ *See* 21 C.F.R. §§ 312.32(c)(1), 312.305(c)(4).

¹⁸¹ Barone, *supra* note 117.

¹⁸² Leonard, *supra* note 15.

¹⁸³ Gorski, *supra* note 31.

This process may be weakened if large numbers of people obtain experimental treatments through state law because it will become more difficult to find participants for clinical trials.¹⁸⁴ Ultimately, this could result in an even longer premarket drug approval process, further prolonging the time before promising new drugs become available to everyone.¹⁸⁵

3. *Pose Threat of More Harm than Good*

Finally, opponents of Right to Try laws argue that the laws threaten to harm the individuals they purport to help by providing access to unproven, potentially dangerous drugs, and offering false hope to patients.¹⁸⁶ Moreover, there is concern that society as a whole could be negatively affected by the state laws. From the perspective of the public health, it is arguably best for drug companies to focus on obtaining drug approval from the FDA, rather than assisting individual patients through Right to Try laws, so that the drugs can be distributed as quickly as possible to the largest number of people who need them.¹⁸⁷

VI. A THREEFOLD SOLUTION

Future action surrounding Right to Try laws entails a series of three steps and requires the cooperation of all three branches of government. Foremost, the FDA should promulgate a regulation explicitly stating that it has sole authority to ensure that safe and effective drugs reach the market and that any state law interfering with its authority is invalid. Second, if states do not abide by this regulatory pronouncement and continue attempts to pass and enforce Right to Try legislation, a party with standing to sue should file a complaint in federal court seeking a declaratory judgment of the legality of the state laws. After analysis of the language of the FDCA, congressional intent, and the Agency's interpretation, which is entitled to deference, a court will likely find that the state statutes encroach upon federal authority. Third, once the state laws are struck down, legislatures and the FDA must work together to reform the current system to ensure that terminally ill individuals are not unnecessarily hindered from gaining access to potentially lifesaving treatment.

¹⁸⁴ Bellamy, *supra* note 82.

¹⁸⁵ Dennis & Cha, *supra* note 27.

¹⁸⁶ Gorski, *supra* note 31 (challenging supporters who claim there is little harm in providing little-tested drugs to the terminally ill: "If there's anything worse than dying prematurely of a terminal illness, it's accelerating your demise, suffering unnecessarily during the little time you have left, and/or emptying your bank account while doing either or both of these things.").

¹⁸⁷ Cha, *supra* note 174; *see also* Dresser, *supra* note 5, at 1645 (noting that commentators defending the FDA's access restrictions believe that "the public, as a body, merits protection from interference by individual members of society" (quoting Elizabeth Weeks Leonard, *The Public's Right to Health: When Patient Rights Threaten the Commons*, 86 WASH. U. L. REV. 1335, 1384 (2009))).

The FDA has decades of experience regulating drugs and is well equipped to make vital and needed changes to the current system in order to streamline and modernize the drug approval process as it applies to those individuals who need access the most.

A. Agency Action: Promulgation of Regulation Explicitly Establishing Federal Authority

Congress has granted authority to the FDA to enforce the FDCA and promulgate regulations consistent with the scope of the Act.¹⁸⁸ Moreover, the 1962 amendments to the FDCA made it unlawful for anyone to market drugs that the Agency has not approved.¹⁸⁹ To date, the FDA has declined to take a position on Right to Try laws; however, in a recent statement the Agency did express concern about any efforts that might undermine the “congressionally-mandated authority and agency mission to protect the public from therapies that are not safe and effective.”¹⁹⁰ The FDA should further expound upon this statement and promulgate a regulation or guidance explicitly stating its opinion that Right to Try laws infringe upon the Agency’s delegated power, are invalid, and should not be followed.¹⁹¹ Should the FDA make such a

¹⁸⁸ See FDCA §§ 302–304, 21 U.S.C. §§ 332–334 (2012).

¹⁸⁹ FDCA § 505(a), 21 U.S.C. § 355(a) (as amended by Drug Amendments of 1962, Pub. L. No. 87-781 § 104(a), 76 Stat. 780, 784).

¹⁹⁰ Dennis & Cha, *supra* note 27 (quoting an FDA statement).

¹⁹¹ There is a chance that political pressures may prevent the FDA from actively opposing Right to Try laws given the laws’ emotional subject matter. If the public perceives the federal government as seeking to impede states’ abilities to provide access to potentially lifesaving drugs, this will not place the Agency in a tenable position. Instead, the FDA could take an approach akin to the one it has taken regarding state marijuana legalization laws, choosing not to enforce the federal law and instead hoping that drug manufacturers will be unwilling to provide the drugs, rendering the laws ineffective as a practical matter. See Ryan J. Reilly & Ryan Grim, *Eric Holder Says DOJ Will Let Washington, Colorado Marijuana Laws Go Into Effect*, HUFFINGTON POST (Aug. 29, 2013), http://www.huffingtonpost.com/2013/08/29/eric-holder-marijuana-washington-colorado-doj_n_3837034.html [<https://perma.cc/6N9Y-AWVT>]; see also Adriance, *supra* note 178, at 154.

However, there are notable differences between state marijuana laws and Right to Try legislation, which suggest that federal passivity makes little sense regarding the latter. It seems unlikely that the FDA would be willing to passively accept Right to Try laws because they will hinder the Agency’s ability to collect data and monitor unapproved drugs that have been given to patients, and might also cause clinical trial participation to decline, delaying ultimate market approval of new drugs. Moreover, without the FDA’s affirmative endorsement of Right to Try laws, drug companies will not be incentivized to provide experimental drugs. *Id.* Drug companies will be unable to recoup the costs of manufacturing small quantities of a drug to those terminally ill patients who qualify under the state laws, and may believe the money is better spent focusing its resources on the drug development and FDA approval process. *Id.* at 155. On the other hand, this is not the case with marijuana laws, where suppliers can produce large quantities of the drug to not only recoup costs, but also realize significant profits. See *id.* at 154.

pronouncement, it is unlikely that any drug manufacturer would be willing to provide drugs under the guise of Right to Try legislation, essentially rendering the laws a practical nullity.¹⁹²

B. *Judicial Declaration: Validity of Right to Try Laws*

Frank Burroughs, founder of the Alliance and avid proponent of Right to Try legislation, admits that a lawsuit challenging the legality of these statutes is necessary: “[A lawsuit challenging state Right to Try laws] wouldn’t be all bad news because it would further elevate this issue in the public arena and put pressure on Congress and the FDA to make this change.”¹⁹³ Once the FDA has made its position on the state legislation clear, a party with standing to sue, such as a drug manufacturing company, should seek declaratory relief in court as to the validity of Right to Try laws.¹⁹⁴

It is likely that such laws will be struck down by a federal court based upon the language of the FDCA, indication of congressional intent, and the FDA’s own regulations and interpretations.¹⁹⁵ While there is no express preemption clause included within the FDCA, the Act does grant exclusive authority to the FDA to initiate enforcement proceedings against drug companies that fail to comply with the FDCA and applicable regulations.¹⁹⁶ Moreover, the 1962 amendments allow for federal preemption when a state law is in “direct conflict” with the FDCA.¹⁹⁷ Further evidence that Congress intended for the FDA to have sole authority to govern this issue can be found in the legislative history of the Act.¹⁹⁸ Additionally, the executive branch has commented that “regulating the safety of drugs . . . is appropriate to the federal government, since the products being regulated are usually marketed on a nationwide basis.”¹⁹⁹

¹⁹² See Adriance, *supra* note 178, at 154 n.36.

¹⁹³ *Id.* at 157 (alteration in original) (quoting Ollove, *supra* note 1).

¹⁹⁴ Another option is for a state to seek an advisory opinion from the Commissioner of the FDA regarding whether Right to Try laws are preempted. Although the regulation authorizing this course of action applies only to “state and local medical *device* requirements,” 21 C.F.R. § 808.5 (2015) (emphasis added), it may nonetheless be used to challenge the legality of Right to Try laws because such laws can apply to experimental medical devices as well. Right to Try Model Legislation, *supra* note 15, § 2(1) (stating that a drug manufacturer may make available to Eligible Patients “an investigational drug, biological product, *or device*” (emphasis added)). Should the Commissioner find the laws unconstitutional, a court would give this decision considerable weight upon review. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996).

¹⁹⁵ See *supra* Part IV for a detailed analysis of why Right to Try laws are preempted under the Supremacy Clause.

¹⁹⁶ FDCA § 310(a), 21 U.S.C. § 337(a) (2012).

¹⁹⁷ See *supra* Part II.A.1.

¹⁹⁸ See, e.g., S. REP. NO. 109-92, at 145 (2005) (stating that the FDA is responsible for the lifecycle of drugs, including premarket review).

¹⁹⁹ PRESIDENTIAL TASK FORCE ON REGULATORY RELIEF, REGAN ADMINISTRATION REGULATORY ACHIEVEMENTS 51 (1983).

Finally, whether the Agency issues a new regulation or guidance on an existing one, such promulgation will be entitled to deference by courts.²⁰⁰

Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the [FDCA], the agency is uniquely qualified to determine whether a particular form of state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” and, therefore, whether it should be pre-empted.²⁰¹

In *Medtronic v. Lohr*, the Supreme Court stated that even where a statute does not explicitly recognize preemption, “the congressional grant of authority to the agency on the matter contained within [the statute in question]—provide[s] a ‘sound basis,’ for giving substantial weight to the agency’s view of the statute.”²⁰²

In 2013, for example, the FDA issued draft guidance to clarify the regulations surrounding its compassionate use program.²⁰³ In this guidance, the FDA stated that it “has a long history of facilitating access to investigational drugs for treatment use for patients with serious or immediately life-threatening diseases or conditions who lack therapeutic alternatives.”²⁰⁴ This statement would be taken into account and given deference by a court²⁰⁵ in concluding that the totality of textual, legislative, and regulatory evidence surrounding the authority of the FDA implores the conclusion that Right to Try legislation must fail.

C. Legislative Reform: Procedural and Substantive Measures

While Right to Try laws will almost certainly not withstand judicial scrutiny, there is some indication that these laws have already served a

²⁰⁰ See, e.g., *Medtronic v. Lohr*, 518 U.S. 470, 496 (“[I]n most cases a state law will be pre-empted . . . to the extent that the FDA has promulgated a relevant federal ‘requirement.’”).

²⁰¹ *Id.* (footnote omitted) (citation omitted) (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

²⁰² *Id.* (quoting *id.* at 509 (O’Connor, J., concurring in part and dissenting in part)); see also *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714 (1985) (considering FDA understanding of preemptive effect of its regulations “dispositive”). But see *Wyeth v. Levine*, 555 U.S. 555, 575–77 (2009) (finding that a conclusory statement in the preamble to a 2006 FDA regulation was not entitled to any weight).

²⁰³ FDA, GUIDANCE FOR INDUSTRY (DRAFT): EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE—QS & AS 1 (May 2013), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351261.pdf> [https://perma.cc/YZ8H-MAY8].

²⁰⁴ See *id.* at 2.

²⁰⁵ *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (holding that when an agency interprets its own regulations it is entitled to near-absolute deference unless the interpretation is “plainly erroneous or inconsistent with the regulation” (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 359 (1989))).

valuable purpose in incentivizing the FDA to consider potential reforms.²⁰⁶ On February 4, 2015, the FDA announced a new streamlined process for expanded access requests for individual patient INDs.²⁰⁷ These draft guidelines include proposed Form 3926, which physicians complete when requesting access to an investigational drug outside of a clinical trial for a patient “who has a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.”²⁰⁸ According to the Agency, Form 3926 “will significantly decrease the amount [of] time it takes to request expanded access for individual patients.”²⁰⁹

This new proposed measure is probably in response to Right to Try legislation, as the major criticism of the federal process which state laws sought to remedy was the lengthy time it took physicians to request expanded access for terminally ill individuals through the compassionate use program.²¹⁰ Furthermore, the FDA is also preparing to offer “concierge assistance” to physicians completing expanded access paperwork to further alleviate the time burden on these sponsors.²¹¹

²⁰⁶ In fact, at least one scholar argues that Right to Try laws are nothing more than tools of persuasion used to draw national attention to the issue of access that is being hampered by bureaucracy. *See generally* Adriance, *supra* note 178.

²⁰⁷ FDA, GUIDANCE FOR INDUSTRY (DRAFT): INDIVIDUAL PATIENT EXPANDED ACCESS APPLICATIONS: FORM FDA 3926, at 1 (Feb. 2015) [hereinafter FDA GUIDANCE: EXPANDED ACCESS], <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM432717.pdf> [<https://perma.cc/EN6H-GAPV>]; *see also* “Right to Try” *Experimental Prescription Drugs: State Laws and Legislation for 2014 & 2015*, NAT’L CONFERENCE OF STATE LEGISLATURES (Mar. 16, 2015), <http://www.ncsl.org/documents/health/RighttoTry2015.pdf> [<https://perma.cc/P3J8-W49R>].

²⁰⁸ FDA GUIDANCE: EXPANDED ACCESS, *supra* note 207, at 3. The FDA intends for this condensed form to comply with the IND submission requirements of sections 312.23, 312.305(b), and 312.310(b). *Id.* at 3–4.

²⁰⁹ *Physician Request for an Individual Patient IND under Expanded Access for Non-emergency or Emergency Use*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm107434.htm> [<https://perma.cc/UB4H-GF3F>] (last updated Mar. 15, 2016); *see also* Individual Patient Expanded Access Applications: Form FDA 3926, 80 Fed. Reg. 7318 (Feb. 10, 2015) (to be codified at 21 C.F.R. pt. 312).

²¹⁰ *See* Alison Bateman-House et al., *Right-to-Try Laws: Hope, Hype, and Unintended Consequences*, 163 ANNALS INTERNAL MED. 796, 796 (2015). The previous individual compassionate use application was alleged to take a physician 100 hours to complete; on the contrary, the new form supposedly can be completed in forty-five minutes. *Id.*; *see also* Peter Lurie, *A Big Step to Help the Patients Most in Need*, FDA VOICE (Feb. 4, 2015), <http://blogs.fda.gov/fdavoices/index.php/2015/02/a-big-step-to-help-the-patients-most-in-need/> [<https://perma.cc/T3UH-KHBC>]. In his blog, the associate FDA commissioner for public health strategy and analysis wrote that the new draft form was in response to concerns from patients and physicians that the process for gaining access to experimental treatments was too difficult. *Id.*

²¹¹ Bateman-House, *supra* note 210, at 796.

There is no doubt that this newly issued guidance is an important first step in reforming FDA regulations governing expanded access and signals that the FDA is willing to listen. Additionally, as the idea of Right to Try laws have percolated to states across the country, legislative reform at the national level now seems like a tangible possibility. In July 2015, the Goldwater Institute partnered with three federal lawmakers to introduce a national version of Right to Try legislation in the U.S. House of Representatives.²¹² The bill is intended to eliminate any potential conflicts between state Right to Try laws and current federal regulations regarding the administration of investigational drugs and is currently undergoing review by the Committee on Energy and Commerce and the Committee on the Judiciary.²¹³ Prior national efforts to reform the FDCA and expand access for terminally ill patients never gained momentum,²¹⁴ but supporters hope that the Right to Try movement has stimulated enough national discussion to make the bill successful this time around.²¹⁵

State and national legislators, as well as the Goldwater Institute, Abigail Alliance, and other supporters of increased access should continue to petition for federal reform of the compassionate use program. While the newly created Form 3926 will cut down on physician paperwork, the next wave of reforms should seek to incentivize drug manufacturers to provide the experimental treatments. For example, FDASIA, recently passed in 2012, provides for the Agency’s ability to collect user fees to aid it in carrying out its mission.²¹⁶ Perhaps some of these fees can be used to subsidize the costs of providing

²¹² Right to Try Act of 2015, H.R. 3012, 114th Cong. (2015); Ed Silverman, ‘Right to Try’ Laws Wrong to Skirt FDA, BOS. GLOBE (Oct. 12, 2015), <https://www.bostonglobe.com/business/2015/10/12/right-try-laws-are-wrong-usurp-fda/54tICnBEQ4DHMlkYd1ZIdJ/story.html> [<https://perma.cc/8JS6-Q6B7>].

²¹³ Steven Ross Johnson, *House Lawmakers Introduce Federal ‘Right to Try’ Bill*, MODERN HEALTHCARE (July 15, 2015), <http://www.modernhealthcare.com/article/20150715/NEWS/150719940> [<https://perma.cc/VC9Y-WM3E>]. The stated purpose of the proposed legislation is to “authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law.” H.R. 3012, pmb1. Further, Section 2 of the bill explicitly references the FDCA in noting that notwithstanding that Act or “any other provision of Federal law, the Federal Government shall not take any action to prohibit or restrict the production, manufacture, distribution, prescribing, dispensing, possession, or use of an experimental drug, biological product, or device that . . . is intended to treat a patient who has been diagnosed with a terminal illness.” *Id.* § 2(a)(1).

²¹⁴ See Leonard, *supra* note 15; see also Dresser, *supra* note 5, at 1639 (citing Access, Compassion, Care, and Ethics for Seriously Ill Patients Act, S. 1956, 109th Cong. (2005)). The 2005 bill was reintroduced in the House in June 2008. H.R. 6270, 110th Cong. (2008).

²¹⁵ While this bill serves as evidence that reform at the national level may be possible, it is somewhat misguided, as its ultimate purpose is to ensure the preservation of Right to Try laws in the face of a judicial challenge. However, because there is reason to doubt the effectiveness of these laws, national legislation must instead seek to reform the FDA compassionate use program directly.

²¹⁶ Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. No. 112-144, §§ 101–408, 126 Stat. 993, 996–1039 (2012) (codified as amended in scattered sections of 21 U.S.C.).

experimental drugs to individual patients. Additionally, the FDA needs to continue to work closely with individuals to secure access agreements from manufacturers. With the FDA's involvement, drug manufacturers will be reassured that providing early access to investigational drugs will not expose them to liability down the line or jeopardize ultimate market approval.

VII. CONCLUSION

Right to Try laws, while well intentioned, are preempted by the FDCA and are thus invalid. As the sole regulator of the premarket drug approval process, it is imperative that the FDA continues its reform efforts. Right to Try laws have served as an important impetus to the Agency in improving its outdated methods, including as recently as February 2015, when it promulgated a new, more streamlined application process for compassionate use. Legislators, regulators, and the public alike should continue to listen to institutions such as the Goldwater Institute and Abigail Alliance and determine how unapproved yet promising new drugs can best reach the hands of those individuals who desperately need them the most. If and when Right to Try laws are declared unconstitutional, the attention will shift to the federal stage and the FDA must rise to the occasion. It must strive to balance safety with increased access so that individuals, on the one hand, will not suffer horrific side effects like those experienced by Joe Malinowski, but on the other, will be provided with the opportunity, like Austin Leclaire so desperately hoped for, of the right to try.